

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
MARSHALL DIVISION**

ALLERGAN, INC., Plaintiff, v. TEVA PHARMACEUTICALS USA, INC., AKORN, INC., MYLAN PHARMACEUTICALS INC., and MYLAN INC., Defendants.	Civil Action No. 2:15-cv-1455-WCB LEAD JURY TRIAL DEMANDED
ALLERGAN, INC., Plaintiff, v. INNOPHARMA, INC., Defendant.	Civil Action No. 2:15-cv-1504-WCB
ALLERGAN, INC., Plaintiff, v. FAMY CARE LIMITED, Defendant.	Civil Action No. 2:16-cv-0401-WCB
ALLERGAN, INC., Plaintiff, v. TWI PHARMACEUTICALS, INC. and TWI PHARMACEUTICALS USA, INC. Defendants.	Civil Action No. 2:16-cv-0820-WCB

**OPPOSED MOTION TO AMEND THE STIPULATED PROTECTIVE ORDER IN
CIVIL ACTION NO. 2:16-cv-0401 AS TO DEFENDANT FAMY CARE LIMITED ONLY**

Public Version Confidential Material Omitted

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INTRODUCTION

Defendant Famy Care Limited (“FCL”) consents to the substantive terms of the Stipulated Protective Order (“Order”) (Dkt. No. 86)¹ in their entirety. But despite considerable effort, FCL has been unable to reach agreement with Plaintiff Allergan, Inc. (“Allergan”) to grant FCL’s designated non-lawyer litigation supervisors access to confidential information. FCL is a foreign corporation with no in-house counsel, and this impasse impedes FCL’s ability to communicate with and direct its litigation counsel. FCL therefore respectfully urges the Court to modify the relevant provisions of the Order as applicable *in this case only* (Civil Action No. 2:16-cv-0401-WCB) to allow FCL to designate non-lawyer representatives as if they were in-house counsel. (*See* Ex. 1 – Proposed Modified Protective Order (adding “In-House Representatives” to § 1 (Definitions), § 5(a)(ii) (disclosure provisions), and § 6(a)(viii) (patent prosecution bar)).² These modest amendments would grant FCL’s litigation supervisors access to Allergan’s information on the same terms as other designees: subject to the same obligations, the same patent prosecution bar, and the same FDA correspondence bar.

FCL has designated three representatives from Lupin Pharmaceuticals, Inc. (“LPI”) and related Lupin entities including Lupin Limited (with LPI, collectively “Lupin”) to supervise this case.³ As described in the attached declarations, Lupin’s Intellectual Property Management

¹ Docket Number citations are to Case No. 2:15-CV-1455-WCB unless otherwise noted.

² Exhibit 2 is a redlined document showing the differences between the Order and the Proposed Modified Protective Order.

³ A Lupin entity, [REDACTED] entered an agreement with FCL regarding the proposed ANDA product. The agreement grants Lupin the authority to supervise and control the litigation. FCL is the ANDA-holder; [REDACTED] and LPI will distribute the product in the US market. (*See* [REDACTED] (Ex. 3)). Allergan has known of this relationship since FCL produced its ANDA on June 6, 2016. Lupin [REDACTED] have produced documents to Allergan regarding this relationship and [REDACTED]

Group (“IP Management Group”) supervises and directs FCL’s litigation counsel. The three FCL designees include one attorney, Ms. Minaksi Bhatt, LPI’s Vice President of Intellectual Property; and Ms. Rachita Naidu and Mr. Manish Mundra—two non-lawyer litigation supervisors in Lupin’s IP Management Group. These representatives review and approve: every FCL filing; FCL’s contentions; FCL’s discovery responses; and will review FCL’s expert reports. The IP Management Group also updates FCL and Lupin management.

FCL’s ability to supervise this case has already been hampered by its designees’ inability to review protected information—for example, requiring a costly and time-consuming redaction and approval process during claim construction briefing. This issue becomes even more pressing as expert discovery approaches, when reports will address secondary considerations of nonobviousness such as alleged unexpected results or commercial success. FCL’s in-house representatives must be able to meaningfully and timely review the expert reports to evaluate the issues, direct litigation counsel and represent FCL’s interests.

Allergan has flatly refused to agree to any non-lawyer in-house representatives, but has articulated no other concern about FCL’s proposed designees. Allergan’s position runs counter to governing law, and does not justify excluding FCL’s designees. No profession has a corner on virtue, so the law focuses on the risk of *inadvertent* disclosure of confidential information to competitive decision-makers, or inadvertent use of such information by competitive decision-makers. *See U.S. Steel Corp. v. United States*, 730 F.2d 1465, 1467-68 (Fed. Cir. 1984); *PACid Grp., LLC v. Apple, Inc.*, No. 6:09-CV-143, 2010 WL 10094684, at *2-3 (E.D. Tex. Feb. 19, 2010). By any reasonable estimate, that risk here is vanishingly small.

First, the disputed in-house representatives—Ms. Naidu and Mr. Mundra—supervise patent cases for a living. They do not research or develop products, or participate in competitive

business decision-making. Ms. Naidu and Mr. Mundra have been admitted under protective orders in other U.S. patent cases—including Eastern District of Texas cases and cases involving Allergan and its affiliates. They supervise outside counsel and update their superiors and in-house “clients”—functions mirroring those of in-house counsel. Ms. Naidu and Mr. Mundra have executed undertakings and abided by protective orders in other cases with no alleged violations; Allergan has no reason to doubt their integrity.

Second, there is also little risk of any actual harm to Allergan from inadvertent disclosure of confidential information. FCL has already filed its ANDA for a proposed generic version of Restasis® with the FDA. That ANDA discloses how the proposed FCL cyclosporine ophthalmic emulsion was developed, made and tested, and FCL must adhere to it. At this stage, Allergan’s confidential information has little competitive value to FCL. Indeed, Allergan has never identified any clearly defined, serious injury that might result from disclosure of its confidential information to FCL’s non-lawyer litigation supervisors, which undermines its position. *See Pansy v. Borough of Stroudsburg*, 23 F.3d 772, 786 (3d Cir.1994).

In short, Ms. Naidu and Mr. Mundra pose no greater risk of inadvertent disclosure or use of Allergan’s confidential information than any in-house counsel. The Court should adopt FCL’s proposed amendment to the Protective Order, and permit FCL to designate Ms. Minaksi Bhatt, Ms. Rachita Naidu, and Mr. Manish Mundra as its In-House Representatives.

FACTUAL BACKGROUND

This protective order dispute between FCL and Allergan arose after FCL was consolidated into this case and plunged into a whirlwind cycle of claim construction briefing and accelerated fact discovery. A summary of the timeline follows:

Allergan sued FCL on April 12, 2016. (*See* Complaint, 2:16-CV-0401-WCB (Dkt. No. 1)). FCL responded on June 6, 2016. (*See* Answer, 2:16-CV-0401-WCB (Dkt. No. 23)). The FCL case was consolidated with the lead cases on June 16, 2016 (*see* Order, 2:16-CV-0401-WCB (Dkt. No. 32)).

The FCL case joined the lead cases amidst the first round of claim construction briefing.⁴ The *Markman* hearing was held on August 26, 2016 (Dkt. No. 178), and a round of supplemental briefing followed.⁵ At the same time, FCL was providing accelerated fact discovery. For example, FCL served its initial disclosures on July 18, 2016 (*see* Dkt. No. 158), and its initial non-infringement and invalidity contentions on July 29, 2016 (*see* Dkt. No. 169). FCL produced documents to Allergan on June 6, 2016; June 20, 2016; November 14, 2016; and December 12-13, 2016, with supplemental productions on January 6, 2017 and January 17, 2017. FCL timely responded to Allergan's written discovery requests, produced two corporate designees for deposition in January 2017, and served Amended Invalidity Contentions (and produced related documents) on February 1, 2017.

FCL first proposed modifying the Order to allow its litigation supervisors access to Allergan confidential information in September, 2016 when the parties began negotiating the scope of e-mail discovery. (*See* Ex. 4 (September 9, 2016 email from J. Polivick to K. Reardon *et al.*)). The parties' contacts on this issue continued through October. At Allergan's request, FCL confirmed in early November 2016 that Ms. Bhatt, Ms. Naidu, and Mr. Mundra were not

⁴ The parties filed the Joint Claim Construction and Prehearing Statement on June 9, 2016 (Dkt. No. 138). Allergan filed its Opening Claim Construction Brief on July 14, 2016 (Dkt. No. 155). Defendants filed their Responsive Claim Construction Brief on August 5, 2016 (Dkt. No. 165). Allergan filed its Reply on August 12, 2016 (Dkt. No. 171).

⁵ Allergan filed its Supplemental Claim Construction brief on September 26, 2016 (Dkt. No. 185). Defendants' Supplemental brief followed on October 26, 2016 (Dkt. No. 190), with Allergan's Reply on November 7, 2016 (Dkt. No. 191).

involved in product development decisions. (*See* Ex. 5 (November 2, 2016 email from J. Polivick to K. Reardon *et al.*)). Allergan nonetheless refused to accept FCL's non-lawyer representatives as designees under the Order. (*See* Ex. 6 (November 3, 2016 email from J. Herriges to J. Polivick *et al.*)). FCL continued to raise this issue with Allergan to try to avoid motions practice, and the parties agreed in mid-January to meet and confer about the procedures for a potential joint submission to the Court. (*See* Ex. 7 (January 18, 2017 emails from P. Curtin to J. Herriges, *et al.* and from J. Herriges to P. Curtin, *et al.*)). When the parties were finally able to arrange a call, Allergan stated it was not interested in a joint filing, so the parties discussed an expedited briefing schedule. (*See* Ex. 8 (February 1, 2017 e-mails from W. Lackey to J. Herriges, *et al.* and from J. Herriges to W. Lackey, *et al.*)).

As described above, FCL seeks to amend the Order because it has no in-house counsel and relies on Lupin's IP Management Group to supervise and direct outside litigation counsel. Lupin's IP Management Group is composed of non-attorney litigation supervisors. FCL was not involved in negotiating the Order as entered in January 2016, and could not have agreed to the disputed terms. The consolidation order in this case did not specifically address the Order, so FCL was uncertain whether the Order applied.⁶ Even so, FCL participated in expedited discovery in good faith to move forward towards the August 2017 trial.

⁶ The order consolidating InnoPharma, Inc. with the lead case addressed the procedure for amending the existing protective order while consolidating those cases. (*See* Order, Dkt. No. 43, filed Oct. 29, 2015 ("The Court will enter one docket control order, one protective order, and one discovery order that will govern the entire consolidated case. If a ... protective order ... has been entered in the lead case at the time new member cases are added to the consolidated action, all parties are directed to meet and confer in order to determine whether amendments to such documents are necessary. Any proposed amendments to the ... protective order ... shall be filed within two weeks of this Order.")). There is no such language in the FCL consolidation order. (*See* Ex. 9, Order, 2:16-CV-0401 (Dkt. No. 32)).

FCL accepts the existing Order (Dkt. No. 86) except for this dispute over Section 5(a)(ii) (and the related definitions), governing the access of designated in-house employees to confidential materials. As noted above, FCL has requested as its three designated representatives: Minaksi Bhatt, Rachita Naidu, and Manish Mundra. Ms. Bhatt is a licensed attorney and LPI's Vice President of Intellectual Property, while Ms. Naidu and Mr. Manish are litigation supervisors in Lupin's IP Management Group. Allergan has agreed to allow Ms. Bhatt access under the Order, but rejects Ms. Naidu and Mr. Mundra because they are not lawyers.

STATEMENT OF LAW

"The court may, for good cause, issue an order to protect a party or person from annoyance, embarrassment, oppression, or undue burden or expense. . . ." Fed. R. Civ. P. 26(c)(1). Under this rule, the Court may enter appropriate protective orders to restrict access to trade secrets or other confidential information. *See* Fed. R. Civ. P. 26(c)(1)(G).

The party seeking a protective order generally bears the burden of establishing good cause. *In re Terra Int'l, Inc.*, 134 F.3d 302, 306 (5th Cir.1998). When parties agree to the entry of a protective order but differ on the terms, the party seeking to limit discovery bears the burden of showing good cause to protect the information and limit disclosure. *See PACid Grp.*, 2010 WL 10094684, at *2 (E.D. Tex. Feb. 19, 2010); *Document Generation Corp. v. Allscripts, LLC*, Case No. 6:08-CV-479, 2009 WL 1766096, at *2 (E.D. Tex. June 23, 2009); *iLife Techs., Inc. v. OnAsset Intelligence, Inc.*, Case No. 3:12-CV-05155-M-BK, 2013 WL 12126265, at *1 (N.D. Tex. Oct. 22, 2013). As the party seeking to limit disclosure, Allergan must prove the harm it would suffer from granting FCL's litigation supervisors access to confidential information. To do so, Allergan must show "a clearly defined and serious injury" from the disclosure. *See Pansy*, 23 F.3d at 786; *Document Generation Corp.*, 2009 WL 1766096, at *2 (E.D. Tex. June 23,

2009). Moreover, Allergan must identify the alleged injury “with specificity. Broad allegations of harm, unsubstantiated by specific examples or articulated reasoning” cannot justify denying access to FCL’s designees. *Pansy*, 23 F.3d at 786 (citations omitted).

Allergan may seek to distinguish these cases because they address disputes over the initial entry of a protective order, whereas the Order was negotiated and stipulated in January 2016. But that argument cannot justly apply to FCL’s effort to amend an order it did not negotiate, and which places it at a disadvantage compared to all other parties—who have in-house counsel supervising the case. A party’s fundamental right to the information needed to seek advice from and effectively direct its litigation counsel cannot change depending on whether the dispute concerns an initial order or a proposed amendment.

“A party to litigation has a more fundamental interest in access to information than retained counsel.” *Phillip M. Adams & Assoc., LLC v. Dell, Inc.*, No. 1:05-cv-64, 2006 WL 4523602, at *6 (D. Utah June 12, 2006). When deciding whether a protective order should bar a party’s attorney or employee from accessing information, courts must weigh the risk of inadvertent disclosure against the potential for the protective order to impair that party’s ability to prosecute or defend its claims. *See U.S. Steel*, 730 F.2d at 1467-68. To do so, courts must carefully examine the facts surrounding each disputed individual’s activities, association, and relationship with the party. *See id.* at 1468. Factors to consider include: (1) whether the person receiving the confidential information is involved in competitive decision making or scientific research relating to the subject matter of the patent, (2) the level of risk of inadvertent disclosure of proprietary information, (3) the hardship imposed by the restriction, (4) the timing of the remedy, and (5) the scope of the remedy. *Round Rock Research, LLC v. Dell Inc.*, No. 4:11-CV-332, 2012 WL 1848672, at *2 (E.D. Tex. Apr. 11, 2012).

The Federal Circuit has defined “competitive decision-making” as “advice and participation in any or all of [a business's] decisions (pricing, product design, etc.) made in light of similar or corresponding information about a competitor.” *U.S. Steel*, 730 F.2d at 1468 n.3; accord *In re Deutsche Bank Trust Co. Americas*, 605 F.3d 1373, 1377–78 (Fed.Cir.2010); see also *Matsushita Electric Indus. Co. v. United States*, 929 F.2d 1577, 1580 (Fed.Cir.1991) (“the standard is not regular contact with other corporate officials who make policy, or even competitive decisions, but advice and participation in competitive decision-making” (internal quotation marks omitted)). The ultimate goal must be to determine whether access creates “an unacceptable opportunity for inadvertent disclosure.” *U.S. Steel Corp.*, 730 F.2d at 1467-68. Granting access to FCL’s litigation supervisors creates no such risk.

ARGUMENT

In this case, the five *Round Rock* factors weigh in favor of FCL’s request for access, taken individually and on balance:

- Ms. Naidu and Mr. Mundra are not involved in competitive or product development decisions. They serve essentially the same role as U.S. in-house counsel. (Declaration of Rachita Naidu (Ex. 10) at ¶¶3-5; Declaration of Manish Mundra (Ex. 11) at ¶¶3-5).
- the risk of inadvertent disclosure and use of Allergan’s proprietary information is correspondingly low;
- allowing Ms. Naidu and Mr. Mundra access to confidential information imposes no significant hardship on Allergan, while not allowing them access has already imposed and would continue to impose hardship on FCL by hampering its ability to timely consult with litigation counsel and supervise this case;
- the timing of the remedy favors FCL because the close of fact discovery is nigh, and expert discovery is soon to begin; and
- the requested remedy is narrow.

In sum, granting Ms. Naidu and Mr. Mundra access to Allergan's confidential information does not create an unacceptable, or even increased, risk of inadvertent disclosure as compared to an in-house counsel, while continuing to restrict access needlessly burdens FCL. This is particularly true because both Ms. Naidu and Mr. Mundra have been designated under previous protective orders allowing them to receive and review confidential information of Allergan and its affiliates. With this case moving into expert discovery, FCL's litigation supervisors need access to confidential information to effectively manage this case.

A. Granting Ms. Naidu and Mr. Mundra Access to Confidential Information Would Not Create an Unacceptable Risk of Inadvertent Disclosure.

Ms. Naidu and Mr. Mundra are litigation supervisors in Lupin's IP Management Group. As such, they do not participate in competitive decision-making or scientific research on product development. (Ex. 10 at ¶¶3-5; Ex. 11 at ¶¶3-5). Each fills essentially the role that an in-house litigation counsel would fill. (Ex. 10 at ¶5; Ex. 11 at ¶5). They and their colleagues in Lupin's IP Management Group are regularly included alongside in-house counsel under protective orders in U.S. patent cases, including past litigation between Allergan (or its affiliates) and Lupin. *See, e.g.*, [Proposed] Stipulated Protective Order at 10, *Forest Laboratories, Inc.*⁷ v. *Apotex Corp.*, C.A. No. 13-1602 (SLR) (D. Del. Sept. 17, 2014), ECF No. 88 (Ex. 12) (granting Mr. Mundra and an IP Management Group colleague access to confidential information); Stipulated Protective Order at 9, *Forest Laboratories, LLC v. Lupin Ltd.*, C.A. No. 14-1058-LPS (D. Del. Jan. 23, 2015) ECF No. 59 (Ex. 13) (granting Ms. Naidu access to confidential information); Stipulated Protective Order at 9, *Senju Pharms. Co. Ltd., et al. v. Lupin Ltd.*, C.A. No. 11-0271 (SLR/MPT) (D. Del. Mar. 8, 2012) ECF No. 57 (Ex. 14) (Allergan, as co-Plaintiff, granting

⁷ Forest Laboratories, Inc. is an Allergan affiliate.

access to two members of Lupin’s IP Management Group, including the Associate Director); *see also* Stipulated Protective Order at 3, *Apotex Inc., et al., v. Lupin Ltd., et al.*, C.A. No. 2:15-cv-00599-RWS (E.D. Tex. Dec. 14, 2015) ECF No. 67 (Ex. 15) (granting Ms. Naidu and Ms. Bhatt access to confidential information); Consent Order, *Horizon Pharma, Inc., et al. v. Lupin Ltd., et al.*, C.A. No. 11-cv-04275-MLC-DEA (D.N.J. March 24, 2015) ECF No. 73 (Ex. 16) (granting Ms. Naidu and other IP Management Group personnel access to “Confidential and Attorney Confidential” materials).⁸ Ms. Naidu and Mr. Mundra understand the responsibilities that come with being under a protective order, will sign the undertaking to be bound, and will submit to the Court’s jurisdiction. (Ex. 10 at ¶6; Ex. 11 at ¶6).

Allergan has refused to accept Ms. Naidu and Mr. Mundra simply because they are “non-lawyers outside the Court’s jurisdiction.” (*See* Ex. 6 (November 3, 2016 email from J. Herriges to J. Polivick, *et al.*) First, very few (if any) of the current “in-house counsel” designees likely reside in this district. Second, Allergan has never explained why Ms. Naidu and Mr. Mundra—having been trusted with Allergan’s confidential information in the past, and trusted in other U.S. patent cases—now create an unacceptable risk. Allergan’s refusal seems particularly unreasonable when, like every other designee, Ms. Naidu and Mr. Mundra would sign the undertaking, submit to the Court’s jurisdiction, and be subject to the Order’s patent prosecution and FDA bars. Allergan has articulated no “clearly defined and serious injury” likely to result from the disclosure, much less “with specificity” – and so fails to meet its burden to justify

⁸ *See also* Confidentiality Order at 3, 8-9, *Shire Development LLC et al. v. Lupin Ltd., et al.*, C.A. No. 16-cv-00612-GJH (D. Md. Feb. 6, 2017) ECF No. 40 (Ex. 17) (granting access to IP Management Group member Pavan Vitta); Stipulated Discovery Confidentiality Order at 7-9, *Tibotec Inc., et al. v. Lupin Ltd. et. al.*, C.A. No. 10-5954-WHW-MCA (D.N.J. Dec. 16, 2011) ECF 109 (Ex. 18) (granting “Lupin in-house personnel” access to proprietary and “highly proprietary” information); Stipulated Protective Order at 10, *Forest Laboratories, Inc., et. al. v. Cobalt Laboratories Inc., et al.*, C.A. No. 1:08-cv-00021-LPS (D. Del. Oct. 10, 2008) ECF No. 193 (Ex. 19) (granting access to four Lupin IP Management Group members).

excluding the FCL designees. *See Pansy*, 23 F.3d at 786 (3d Cir.1994).

Allergan's litigation counsel has tried before, unsuccessfully, to bar Ms. Naidu from access to confidential information without onerous restrictions. (*See* Ex. 20 at 20:10-44:24 (June 15, 2015 Hearing Tr., *Iceutica Pty Ltd, et al. v. Lupin Limited, et. al.*, No. CV 14-1515-SLR, (D. Del.))). In *Iceutica*, Plaintiff's counsel argued the dispute was about "whether someone who is not an attorney should have access to those same materials [as in-house counsel], and that's where we draw the line." (*Id.* at 21:9-12). After argument, Magistrate Judge Fallon granted Ms. Naidu access on essentially the same conditions applied to in-house counsel, that she: (1) subject herself to the Court's jurisdiction; (2) agree to be bound by the confidentiality requirements in the protective order; (3) agree to be bound by the rules of professional conduct for Delaware lawyers; and (4) agree to submit to the Court's jurisdiction for enforcement. (*Id.* at 42:2-19).⁹

Another court also recently rejected arguments mirroring Allergan's, and granted protective order access to a Lupin IP Management Group member after letter briefing and argument. (*See* Ex. 17 (February 6, 2017 [Proposed] Confidentiality Order, *Shire Development LLC et al., v. Lupin Ltd., et al.*, C.A. No. 16-cv-00612-GJH (D. Md.))). In *Shire v. Lupin*, Plaintiffs sought to limit in-house access under the protective order to employees "licensed to practice law in the United States and subject to the rules of professional conduct." (Ex. 21 at 2 (Shire Letter Brief, *Shire Development LLC, et al. v. Lupin Ltd., et al.*, C.A. No. 16-cv-00612-GJH (D. Md. Jan. 17, 2017) ECF No. 37)). Lupin argued that its in-house litigation supervisor from the IP Management Group required access to manage the case and supervise counsel. (*See* Ex. 22 at 2, 4 (Lupin Letter Brief, *Shire Development LLC, et al. v. Lupin Ltd., et al.*, C.A. No. 16-cv-00612-GJH (D. Md. Jan. 17, 2017) ECF No. 38)). Judge Hazel ruled for Lupin, and

⁹ The *Iceutica* hearing transcript serves as Magistrate Judge Fallon's ruling. (*Id.* at 44:11-12).

granted Mr. Vitta access under the Confidentiality Order. (*See* Ex 17 at 8-9). Notably, the *Shire v. Lupin* confidentiality order also includes (at Lupin's request) patent prosecution and FDA correspondence bars very like those in this Order. (*See id.* at 6, 10; *see also* Ex. 22 at 1-3).

Here, as in *Iceutica* and the other cited cases, there is no good reason to bar Ms. Naidu and Mr. Mundra from access to confidential information. Ms. Naidu and Mr. Mundra understand, and will agree to, all required confidentiality obligations on the same terms as in-house counsel designees.¹⁰ (Ex. 10 at ¶¶6-7; Ex. 11 at ¶¶6-7). Absent some real evidence that they place Allergan's confidential information at risk, the Court should allow FCL's designees access under the Order, so they can do their jobs and supervise this case.

B. The Risk of Harm From Inadvertent Disclosure is Low.

Not only is the *risk* of any inadvertent disclosure or use in competitive decision-making low, as shown above, but the nature of the generic pharmaceutical business makes the risk of *harm* from any inadvertent disclosure of Allergan's proprietary information very low. Perhaps unlike Allergan's branded competitors, FCL—as a generic pharmaceutical company having already filed its ANDA—would derive little competitive value from Allergan's confidential information regarding Restasis®. By contrast, brand pharmaceutical companies could inadvertently use the information in a generic ANDA to draft Citizen Petitions intended to erect regulatory barriers to generics, or to amend patent claims to capture proposed generic products; as a practical matter generic companies cannot similarly use confidential information from the brand company. The realities of the pharmaceutical industry make the risk of inadvertent disclosure or use of Allergan's proprietary information even lower than would be the case in a situation involving competitors in a traditional market.

¹⁰ The parties have not discussed terms under which Ms. Naidu and Mr. Mundra could be designated under the Order. Allergan's flat refusal left FCL unwilling to negotiate with itself.

Nonetheless, Ms. Naidu and Mr. Mundra would be subject to the patent prosecution and FDA correspondence bars included in the Order:

[Each] In-House Representative does not have and shall not have for a period of one year from final disposition of this Litigation [as described by the Patent Prosecution Bar in § 12]: (a) direct responsibility for drafting or substantive prosecution of patent applications relating to ophthalmic cyclosporine compositions, or relating to Restasis® or generic equivalents thereto (including Defendants' ANDA Products), and (b) any direct responsibility for any correspondence with the FDA concerning ophthalmic cyclosporine compositions, relating to Restasis®, or generic equivalents thereto (including Defendants' ANDA Products).

(Ex. 1, Proposed Protective Order at § 5(a)(ii)). As noted above, Ms. Naidu and Mr. Mundra are experienced litigation supervisors, and understand the responsibilities imposed by protective orders. Allergan, its affiliates, other U.S. litigants and other federal courts have trusted Ms. Naidu and Mr. Mundra with access to confidential information before, and Allergan has not suggested that the risk of inadvertent disclosure has suddenly changed.

C. Famy Care Faces Hardship Absent Entry of the Amended Protective Order.

Currently, FCL must request redacted versions of every filing or correspondence containing Allergan Confidential information before counsel can share it with the in-house litigation supervisors, and would need to continue this process through expert discovery and trial absent entry of the Amended Protective Order. This process has burdened both sides, and has often delayed and diminished litigation counsel's ability to properly consult with FCL's litigation supervisors. For example, litigation counsel was unable to timely share Allergan's Supplemental Reply Claim Construction Brief responding to the FCL-specific "Cyclosporin A Is the Only Peptide Present" argument with FCL's litigation supervisors because Allergan filed that brief under seal. (Ex. 23 at 1 (November 10, 2016 email from P. Abbott to J. Herriges *et al.*)). Allergan was unwilling to redact a copy of the brief for FCL, so FCL's litigation counsel had to await Allergan's approval of their redactions before sharing the document with the client

representatives. When co-defendants submit briefs or motions containing Allergan Confidential information, they too must provide redacted versions for FCL's review. This cumbersome, costly arrangement means FCL's litigation supervisors sometimes cannot effectively supervise the case or make timely decisions when key documents are delayed and made incomplete through redaction. This problem will only worsen during expert discovery. The redaction process hampers the efficient progress of the case. Beyond slowing and complicating normally routine actions, this process could also impede meaningful settlement negotiations, because FCL's litigation supervisors never have a full picture of the case.

FCL has no desire to burden Allergan or the other defendants, and so consents to the Order in its entirety but for the noted "In-House Representatives" modifications. FCL seeks the same access for Ms. Naidu and Mr. Mundra as the designated in-house counsel, under the same conditions and responsibilities. Allergan and its affiliates have granted Ms. Naidu, Mr. Mundra, and other Lupin IP Management Group members such access before, and Allergan has never explained how or why they now present an unacceptable risk.

D. The Scope and Timing Weigh in Favor of FCL.

The scope and timing of the remedy are the remaining factors for the Court to consider when determining whether FCL's proposed amendments to the protective order are appropriate. *See Round Rock*, 2012 WL 1848672 at *2. As mentioned above, FCL's seeks to narrowly modify the Order to allow its chosen litigation supervisors the same conditional access to confidential information granted to the other parties' in-house counsel. These proposed changes do not disrupt existing document productions or depositions, alter any other parties' responsibilities, or modify the single-tier structure. The proposed remedy is tailored to the sole disputed issue.

The timing also weighs in favor of entering the Amended Protective Order. The close of fact discovery is imminent, and many depositions are being conducted and have been conducted

in the past few weeks. FCL's counsel will not be able to update their supervisors on developments from these depositions, or readily share transcripts. Unless things change, FCL's litigation supervisors will be impeded from reviewing expert reports being prepared for FCL as well as Allergan's responsive expert reports.

In sum, Allergan's refusal to allow Ms. Naidu and Mr. Mundra access to confidential information substantially prejudices FCL's rights and ability to effectively manage this case. Conversely, Allergan will not be prejudiced by allowing Ms. Naidu and Mr. Mundra access to confidential information, as it has in the past. Therefore, the fairest and most efficient course of action is to enter FCL's proposed Amended Protective Order in this case (attached) either on its own or as an addendum to the existing Order.

CONCLUSION

For all of the reasons set forth above, and for good cause shown, FCL requests that the Court enter the proposed Amended Protective Order, attached hereto as Exhibit 1.

Dated: February 6, 2017

Respectfully submitted,

By: /s/ Eric H. Findlay

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Attorneys for Famy Care Limited

CERTIFICATE OF SERVICE

I hereby certify that on February 6, 2017, the foregoing document was served upon all counsel of record via electronic mail in accordance with the Federal Rules of Civil Procedure.

/s/ Eric H. Findlay

Eric H. Findlay

CERTIFICATE OF CONFERENCE

The Parties have complied with the meet and confer requirement in Local Rule CV-7(h). On October 31, 2016 and January 31, 2017, counsel for Plaintiff Allergan Inc. and Defendant Famy Care Limited met and conferred telephonically regarding the Motion and protective order dispute therein. In addition, counsel for the Parties exchanged multiple substantive emails in further efforts to narrow and/or resolve this dispute. The Parties were unable to resolve the dispute or agree on the Motion and are at an impasse, leaving an open issue for the Court to resolve. As a result, Defendant files this Motion, which is opposed by Plaintiff.

/s/ Eric H. Findlay

Eric H. Findlay